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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 21

Serial Number: 08/631470
Filing Date: 4/12/96
Appellant(s): Staley A. Brod

Benjamin Aaron Adler

For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 3/3/99.

(1) Real Party in Interest.

A statement identifying the real party is contained in the brief.

(2) Related Appeals and Interferences.

A statement identifying the related appeals and interferences

which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of claims.

The statement of the status of claims contained in the brief is correct. Claims pending are 1-20.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of invention.

The summary of invention contained in the brief is correct.

(6) Issues.

The appellant's statement of the issues in the brief is correct.

(7) Grouping of claims.

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because although appellant has considered claims 1-20 to lie in four embodiments, claims 1-20 are not separately patentable as grouped since claims 1-7 include in their breadth each of the other

embodiments such that if claims 1-7 stand or fall so should claims 8-20. Indeed, the same may be said of claims 8-12, 13-18 and 19-20 wherein "decreasing severity" is inter-related to "reduction of inflammation" or reducing cytokine levels.

(8) Claims appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of record.

US 5019382	Cummins, Jr.	5/1991
Shibutani et al.	Iyakuhin Kenkyu, vol. 18(4), pages 571-582, 1987.	

(10) New prior art.

No new prior art has been applied in this examiner's answer.

(11) Grounds of rejection.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-4, 6-11, 13-20 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines 12-26, col. 13, and the claims. Such disclosure meets the claims.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claims 5 and 12 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The disclosure is the same as above as discussed for claims 1 and 8. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have

been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

5. Claims 1-20 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view of Shibutani et al. (Iyakuhin Kenkyu, vol. 18(4), pp. 571-82, 1987).

The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

7. Claims 1-12 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention.

There is no support in the specification for terms "immediately upon" oral administration. The specification is limited to and shows that the cytokine was ingested and that it was orally administered.

(13) Response to argument.

On page 9 of the brief, appellant has criticized the Cummins reference for showing only one anecdotal report and being "extremely limited" (see declaration submitted). He argues that "this limited clinical data" cannot be considered enabling and therefore should be held "incredible" and therefore non-anticipatory. Enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation". *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 140, 1404 (Fed. Cir. 1988). The specification and data therein is considered to be adequate to provide the skilled worker enough to practice the invention without "undue experimentation". A patent cannot be called "non-enabling" because appellant has produced data from 27 patients and 18 controls versus the one example in the patent used. See MPEP §2164.02.

As for amounts discussed at page 14 of the brief, the claims rejected under 35 USC 102 do not contain the limitation that appellant has based his arguments on (SEE page 7, lines 1-2 of the response) and as for claim 11 note that the claim is anticipated by Cummins Jr. showing 5 I.U./kg which overlaps with the end point of the claimed range. In this regard see appellant's arguments at page 14 of the brief.

Appellant's discussion of Cummins' mode of

administration at page 13 of the response is also not persuasive. There is nothing clearly distinguishable between "orally administering...such that the ...interferon is ingested after oral administration" (see claim 1) and Cummins' mode. Appellant has argued at page 13 that in his specification the interferon was fed through a needle inserted into the stomach and there was no oral or pharyngeal contact. There are no such limitations in the claims, however, and the relevance of this argument in view of the instantly claimed limitations and claim recitation is not clear. Appellant cannot rely on the specification to impart to the claims limitations not recited therein. Such a reliance is ineffective to define over the prior art. *In re Lundberg,* 244 F2d 543, 113 USPQ 530 (CCPA 1957), *In re Winkhaus,* 188 USPQ 129 (CCPA 1975). See also *In re Hyson,* 172 USPQ 399, *In re Tiffin,* 171 USPQ 294, *In re Lindner,* 173 USPQ 356: It is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims.

Appellant also argues that there was only "brief" exposure of interferon to the oral mucosa in his method. The claims herein do not recite anything to this end and there is no recitation to show such a "brief" exposure only. Appellant's pointing out col. 5, lines 50-55 of Cummins is also unpersuasive. The patent clearly teaches "Daily dosage of interferon....as a single dosage". Nowhere in any statute is there a requirement that only the preferred embodiment of the reference should be considered a teaching and the rest of the reference be ignored. See *In re Uhlig,* 153 USPQ 460, *In re Mills,* 176 USPQ 196 (CCPA 1972)

Both the traversal of the rejection over claim 5 and the declaration have been carefully reviewed and considered and

the above discussions apply here too.

Appellant's traversal of the rejection of claims 1-20 at page 18 is in error. Test for combining references is not what individual references themselves suggest but what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1970). Appellant has improperly criticized the references individually where the rejection is based upon the combined teachings of the references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be established by attacking references taken individually when rejection is based on a combination of references. *Ex parte Campbell* 172 USPQ 91 (BPA&I 1971). Note that Shibutani's abstract is used to show toxicity studies only and the motivation it provides to the artisan to do what appellant has done.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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